



Position Title: Chief Medical Officer
Department: Clinical Development

Our vision is a world where science, passion, and compassion create better todays and more tomorrows.

Company Overview:

Astria Therapeutics (Nasdaq listing, ATXS) was formed following the acquisition of Quellis Biosciences, Inc., by Catabasis Pharmaceuticals in January 2021. Astria is focused on developing its lead program STAR-0215, a potent and long-acting monoclonal antibody plasma kallikrein inhibitor, as the potential best-in-class and most patient-friendly prophylactic treatment option for the prevention of attacks in patient affected by hereditary angioedema. Astria will also seek to develop a pipeline in the areas of allergy and immunology with a focus on rare and niche indications through internal discovery efforts and in-licensing.

Concurrent with the acquisition of Quellis, the Company entered into definitive agreements for a private placement with institutional accredited investors to raise approximately \$110 million. The financing was led by Perceptive Advisors, with participation from Fairmount Funds Management LLC, RACapital Management, Cormorant Asset Management, Venrock Healthcare Capital Partners, Logos Capital, BoxerCapital, Acorn Bioventures, Commodore Capital, Surveyor Capital, Acuta Capital Partners, Sphera Healthcare, and Serrado Capital LLC. As of June 20, 2021, the Company had cash, cash equivalents, and short-term investments of approximately \$140 million. The Company expects that it has sufficient cash to fund its current operating plan through 2023.

Astria is well-poised to continue successfully advancing their current programs — with the STAR-0215 program on track to potentially demonstrate clinical proof of concept of its differentiated profile and long antibody half-life in Phase 1a next year — in addition to growing and developing additional product candidates and partnerships.

STAR-0215:

Astria's lead program, STAR-0215 is currently in preclinical development for the treatment of HAE, a rare genetic disorder characterized by severe, recurrent, unpredictable, painful, and sometimes life-threatening swelling in the face, limbs, abdomen, and airway. Astria is developing STAR-0215 to be a long-acting monoclonal antibody inhibitor of plasma kallikrein, dosed once every 3 months or longer, with the goal of providing the most patient-friendly chronic treatment option for people living with HAE. The company expects to file an Investigational New Drug (IND) application for STAR-0215 in mid-2022 and plans to initiate a Phase 1 clinical trial with initial results anticipated by year end 2022.

Position Overview:

Astria Therapeutics is seeking a Chief Medical Officer (CMO), who, as a member of the company's leadership team, will develop, lead, and drive the clinical development and contribute to the overall R&D strategy of the company. Reporting directly to the Chief Executive Officer, the Chief Medical Officer (CMO) will play a critical role on the senior leadership team of Astria, providing medical expertise in decisions affecting the company's clinical development programs in support of Astria's corporate goals. This well-regarded, highly credible physician or physician-scientist will be responsible for broad-ranging responsibilities for selecting, prioritizing, and accelerating the development efforts of drug candidates through all phases of development to regulatory approval.

The CMO fulfills a critical and highly visible role, making substantial clinical and medical contributions to the company. Charged with the successful strategic positioning and tactical advancement of the company's programs, the CMO assumes ownership over Astria's clinical development, and is responsible for ensuring medical excellence in all development efforts. An individual successful in this role thus will be a broadly skilled leader and communicator with evidence of strategic, tactical, and operational abilities in Research and Development and a significant track record of successful drug development and regulatory filings of therapeutics.

Responsibilities:

- Create the medical vision and global clinical strategy to advance Astria's assets for the benefit of patients.
- Provide clinical leadership and a clinical perspective to the comprehensive strategy across drug discovery, translational research, clinical development, and regulatory activities.
- Advance programs forward from preclinical stage to late clinical stage, utilizing a strong translational research skillset, and execute proof of concept studies that will aid and provide additional information for pivotal studies downstream.
- Drive activities that lead to successful IND and NDA filings for new drug therapies.
- Responsible for clinical development strategies including Phase 1 through 3, lifecycle management, safety responsibilities, medical interactions with regulatory bodies, and interactions with any collaborative partner(s).
- Oversee and/or directly design and author study protocols and interpret clinical study data. Design and implement safety strategy for clinical studies, including regular review of safety data and responses to safety issues. Ensure Astria meets its development and regulatory milestones.
- Provide the clinical voice for Astria at the highest level at the FDA, EMEA and other regulatory agencies.
- Represent Astria both internally and externally vis-à-vis the scientific and business communities including scientific conferences, presentations, industry, and Wall Street.
- Attract and retain a world-class clinical team.
- Maintain understanding of competitors and clinical developments in relevant therapeutic areas by attending scientific meetings and tracking literature.
- Represent and manage the company's programs to diverse audiences including FDA, shareholders, corporate partners, Board of Directors and other key stakeholders.
- Actively assist in seeking product and/or technology alliances with appropriate pharmaceutical partners to enhance/expedite the development of the company's assets.
- Supervise and direct the activities of clinical research and development staff to include Clinical Development, Clinical Operations, and Medical Writing.
- Advocate for the health and well-being of patients.

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- Lead and oversee the strategic definition and tactical development of clinical trials programs, including protocol writing, interpretation of clinical data, and literature reviews.
- Ensure the consistent application of state-of-the-art scientific and ethical methods to design clinical investigational trials of the highest quality.
- Ensure that all clinical trials are in keeping with approved timelines and budgets, with potential obstacles identified and solutions implemented to avoid delays in clinical trial implementation.
- Ensure the work with colleagues and collaborators are coordinated and that all people, systems, processes and materials required for clinical trials are available and appropriately prepared
- Ensure that clinical trials are conducted in accordance with applicable regulatory requirements and guidelines as well as a patient's first mentality.
- Ensure the identification, recruitment and selection of appropriate clinical investigators and contract research organizations, resulting in appropriate negotiation of contracts.
- Ensure timely medical review and reporting of adverse events.
- Assist and actively partner with Regulatory Affairs & Quality Assurance to ensure the timely preparation of documents to be submitted to the FDA and other health authorities for review.
- Ensure the timely preparation of presentations reporting results of clinical trials to internal and external audiences.
- Collaborate with colleagues in discovery research and preclinical development line functions to move product candidates for entry into clinical investigations.
- May represent the Clinical Research line function on multidisciplinary project teams.
- May work with marketing and business development to evaluate product candidates, determine product indications and design post-marketing studies, as appropriate.

Qualifications:

The ideal candidate for the Chief Medical Officer role will have a minimum of 12 years' experience in the biotech or pharmaceutical industry and a record of accomplishment, including developing, planning, directing, and designing clinical studies and direct interactions with regulatory agencies and experience leading clinical development and translational research.

Specific professional experience and qualifications include:

- An M.D. or M.D./Ph.D. with strong leadership skills and proven biopharmaceutical industry experience in leading clinical development.
- At least 15 years of industry experience in drug development, with experience in allergy and/or immunology is a plus. Additional experience with a broad range of therapeutic areas in the rare disease space is preferred.
- Deep scientific and medical knowledge, with a strong understanding of the drug development process, and demonstrated contributions that have led to clinical successes.
- Experience in regulatory submissions to the FDA and other regulatory agencies, including interaction with these agencies on novel trial designs and new indications.
- Proactive, forward thinking, with the ability to think innovatively about clinical development and regulatory strategy and accurately anticipate future consequences and trends.
- The ability to interact and build strong relationships with external Key Opinion Leaders, academic partners and industry experts.
- Previous experience managing direct reports with a proven track record of developing clinical leaders.
- Willingness to be hands on and detail oriented while also seeing the overall big picture.

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- High enthusiasm, independence and self-motivation, with a strong entrepreneurial mindset and “can do” attitude.
- Creative problem-solving skills and relentlessness in pursuit of continuous improvement and efficiency, with a strong sense of urgency.
- Excellent interpersonal and communication skills with the ability to relate to both internal and external stakeholders. Ability to develop strong, positive relationships with colleagues and the Board of Directors.
- Highly developed understanding of the external marketplace.